

APR 11 2001

K010114

## Summary of 510(k) Submission

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**1. Name and  
address of  
submitter**

VISTAKON<sup>®</sup>, Division of Johnson and Johnson Vision Care, Inc.  
7500 Centurion Parkway, Suite 100  
Jacksonville, Florida 32216  
Contact: Sharon A Briggs  
Phone: 904-443-1471  
Date Prepared: January 12, 2001

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**2. Identification  
of Device**

- a. Trade name: ACUVUE<sup>®</sup> 2 COLOURS Brand (etafilcon A) Contact Lens with UV blocker
  - b. Common or Usual Name: Soft (hydrophilic Contact Lens (daily wear)
  - c. Classification : Class II
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**3. Predicate  
Device**

ACUVUE<sup>®</sup> 2 Brand (etafilcon A) Contact Lens clear and with visibility tint with UV Blocker (K962804, concurred on July 18, 1996)

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**4. Description  
of Device**

The ACUVUE<sup>®</sup> 2 COLOURS (etafilcon A) Soft (hydrophilic) Contact Lens is available as a spherical lens, a bifocal lens, a toric lens and a toric bifocal lens. The lens material (etafilcon A) is a copolymer of 2-hydroxyethyl methacrylate and methacrylic acid cross-linked with 1, 1, 1-trimethylol propane trimethacrylate and ethylene glycol dimethacrylate. The ACUVUE<sup>®</sup> 2 COLOURS Contact Lens contains a pigmented area that will mask or enhance the color of the natural iris. The lens is colored with one or more of the following color additives: iron oxides, titanium dioxide, phthalocyaninato (2-) copper, phthalocyanine green, vat orange 1 and reactive blue dye #4. The ACUVUE<sup>®</sup> 2 COLOURS Contact Lens is available in the following opaque colors: Blue, Gray, Green and Honey. They are also available in the following enhancer colors: Blue, Green and Aqua.

In the ACUVUE<sup>®</sup> 2 COLOURS Contact Lens with UV Blocker, a benzotriazole UV absorbing monomer is used to block UV radiation. The UV Blocking for ACUVUE 2 COLOURS averages 97% in the UVB range of 280 nm to 315 nm and 81% in the UVA range of 316 nm to 380 nm.

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## Summary of 510(k) Submission , Continued

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### 5. Intended Use (indications)

The ACUVUE® 2 *COLOURS* Contact Lenses are indicated for daily wear to enhance or alter the apparent color of the eye and/or for the correction of refractive ametropia (myopia and hyperopia) in aphakic or non-aphakic persons with non-diseased eyes who may have 1.00D or less of astigmatism.

The ACUVUE® 2 *COLOURS* (etafilcon A) Soft (hydrophilic) BIFOCAL Contact Lens is indicated for daily wear for the correction of distance and near vision in presbyopic, aphakic or non-aphakic persons with non-diseased eyes who may have 0.75 D of astigmatism or less.

The ACUVUE® 2 *COLOURS* (etafilcon A) Soft (hydrophilic) TORIC Contact Lens is indicated for daily wear for the correction of visual acuity in aphakic or non-aphakic persons with non-diseased eyes that are hyperopic or myopic and may have 10.00 D of astigmatism or less.

The ACUVUE® 2 *COLOURS* (etafilcon A) Soft (hydrophilic) TORIC-BIFOCAL Contact Lens is indicated for daily wear for the correction of distance and near vision in presbyopic aphakic or non-aphakic persons with non-diseased who may have 10.00 D of astigmatism or less.

ACUVUE® 2 *COLOURS* UV Blocking Contact Lenses help protect against transmission of harmful UV radiation to the cornea and into the eye.

The ACUVUE 2 *COLOURS* Contact Lenses may be prescribed for daily wear. Eye Care Practitioners may prescribe the lenses either for single-use disposable wear or frequent/planned replacement wear with cleaning, disinfection and scheduled replacement (see "Wearing Schedule"). When prescribed for frequent/planned replacement wear, the lenses may be disinfected using a chemical disinfection system only.

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## Summary of 510(k) Submission , Continued

6. **Technological Characteristics** The ACUVUE® 2 COLOURS UV Blocking Contact Lenses is classified into FDA Group IV for contact lens materials. The predicate device is classified into FDA Group IV. The characteristics of the ACUVUE® 2 COLOURS UV Blocking Contact Lenses are compared to the characteristics of the predicate device in the following table.

Characteristic	Predicate Device Label Claim	Subject Device Label Claim
% Water Content	58%	58%
Refractive Index @ 20° C	1.40	1.40
Specific Gravity	0.98-1.12 (calculated)	0.98-1.13 (calculated)
Dk (Fatt method, non-edge corrected)	28.0 x 10 <sup>-11</sup> (cm <sup>2</sup> /sec) (ml O <sub>2</sub> /ml x mm Hg)	28.0 x 10 <sup>-11</sup> (cm <sup>2</sup> /sec) (ml O <sub>2</sub> /ml x mm Hg)
Dk (Fatt method, edge corrected)	21.4 x 10 <sup>-11</sup> (cm <sup>2</sup> /sec) (ml O <sub>2</sub> /ml x mm Hg)	21.4 x 10 <sup>-11</sup> (cm <sup>2</sup> /sec) (ml O <sub>2</sub> /ml x mm Hg)
Light Transmission	Minimum 85%	Minimum 70%
Base Curve Radius, mm	7.85 mm to 10.00 mm	7.85 mm to 10.00 mm
Diameter, mm	12.0 mm to 15.0 mm	12.0 mm to 15.0 mm
Center Thickness	Varies with power: 0.06 to 1.00 mm	Varies with power: 0.06 to 1.00 mm
Power, Diopters	-20.00 D to +20.00 D	-20.00 D to +20.00 D

7. **Summary of Non-Clinical Performance Data** The following tests were conducted as recommended by the Premarket Notification (510(k)) Guidance Document for Daily Wear Contact Lenses, revised May 1994:

1. Toxicology Testing;
  - a. Cytotoxicity
  - b. USP Ocular Irritation
  - c. USP Systemic Injection
2. Leachable Monomer and Additive;
3. Physical /Chemical Testing;
4. Stability Testing;

8. **Clinical Studies** No clinical data is required for this submission

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## Summary of 510(k) Submission, Continued

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### 9. Conclusions Drawn From The Studies

The ACUVUE® 2 *COLOURS* Contact Lens is substantially equivalent to the previously cleared ACUVUE® 2 Contact Lens.

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Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

**JUL 17 2001**

Ms. Sharon Briggs  
Manager, Regulatory Submission  
Johnson and Johnson Vision Care, Inc.  
7500 Centurion Pkwy.  
Jacksonville, FL 32256

Re: K010114

Trade Name: ACUVUE® 2 COLOURS Brand (etafilcon A) Soft (hydrophilic) Contact  
Lens with UV Blocker for Daily Wear

Regulation Number: 886.5925

Regulatory Class: II

Product Code: LPL

Dated: January 8, 2001

Received: January 16, 2001

Dear Ms. Briggs:

This letter corrects our substantially equivalent letter of April 11, 2001 regarding the trade name of the device.

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.


If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General (QS) regulation (21 CFR Part 820) and that, through periodic QS inspections, FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register.

Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to continue marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-6413. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at their toll free number (800) 638-2041 or at (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,

  
for

A. Ralph Rosenthal, M.D.

Director

Division of Ophthalmic, and Ear, Nose and  
Throat Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

## Indications Statement

10010114

510(k) Number (if known):

Device Name: ACUVUE® 2 COLOURS Brand (etafilcon A) Soft (hydrophilic) Contact Lens with UV blocker

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PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED  
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over the Counter

Daniel W.C. Brown, Ph.D.  
(Division Sign-Off)  
Division of Ophthalmic Devices

510(k) Number K010114

RECEIVED

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OP  
S.K.H.